REMARKS

Applicants have received and carefully reviewed the Final Office Action of the Examiner mailed May 24, 2010 and the Advisory Action mailed August 6, 2010. Applicants respectfully traverse (and do not concede) all objections, rejections, and adverse assertions made by the Examiner. With this paper, claims 22 and 35 have been amended, claim 27 has been canceled without prejudice, and newly presented claim 37 has been added. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. Claims 22, 24-28, and 30-36 remain pending, with claims 31-34 and 36 previously withdrawn. Favorable consideration of the above amendments and the following remarks is respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 22, 24-28, 30, and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Matsumoto et al. (U.S. Patent No. 4,610,665) in view of Picha et al. (U.S. Patent No. 5,080,654), and further in view of Py (U.S. Patent No. 6,604,561). Applicants respectfully traverse the rejection.

Turning to independent claim 22, which recites:

> 22. A catheter having a vacuum seal, comprising:
> an elongate catheter shaft having a proximal end, a distal end, a guidewire lumen defined therethrough, and an inflation lumen defined therethrough;
> a balloon disposed adjacent the distal end of the catheter shaft, the balloon being in fluid communication with the inflation lumen;
> a port disposed at the proximal end of the catheter shaft, the port having an opening defined therein that is in fluid communication with the inflation lumen and a flanged end; and
> a seal member releasably attached to the flanged end and covering the opening;
> wherein the seal member is self-sealing and has a solid cross-section such that the seal maintains a vacuum within the inflation lumen.

None of Matsumoto et al., Picha et al., or Py taken alone or in combination, appear to teach or suggest a catheter including a releasable seal member including that is self-sealing and has a solid cross-section such that the seal maintains a vacuum within the inflation lumen.

Matsumoto et al. appear to disclose a medical device including a valve body. The valve body appears to be configured to allow an additional medical device, such as a rod-like member,

to pass through the valve body into the medical device. The valve body appears to include two slits crossing perpendicular to each other. When the additional medical device is not inserted into the medical device, the slits appear to maintain a substantially fluid tight seal. The slits appear to allow the additional medical device to pass through the valve body while still maintaining a fluid tight seal. Once the additional medical device has been removed, the slits appear to close and again provide a substantially fluid tight seal. As acknowledged by the Examiner, Matsumoto et al. do not appear to teach or suggest a seal having a solid cross-section or a releasable seal. In formulating the rejection, the Examiner appears to rely on Picha et al. as disclosing a releasable seal and Py as disclosing a seal having a solid cross-section.

Py appears to disclose a resealable cap for a medicament vial. The cap appears to be formed from a material that may be punctured with a needle, such as low density polyethylene. The cap may be punctured with a needle to fill the vial. Once the vial has been filled, Py appears to disclose the cap may be resealed by heating the seal with a laser or direct heat. In formulating the rejection, the Examiner asserts, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Matsumoto and Picha such that the seal comprised a solid cross-section to further ensure fluid cannot pass through the seal unintentionally." Applicants respectfully disagree.

Py appears to disclose the cap needs to be punctured with a needle or other similar device. The puncture appears to generate a hole through the cap which would remain in place unless the cap were resealed using mechanical means. In contrast, Matsumoto et al. appear to disclose a valve member through which any type of device may pass and once the device has been removed, the valve member maintains a substantially fluid-tight seal. It appears that if one were to modify the device of Matsumoto et al. as suggested by the Examiner some type of through hole would need to be created, thus allowing fluid to pass through the valve member when an additional device is not disposed within the valve member. MPEP 2143.01 V states, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)." Matsumoto et al. disclose at column 2, lines 20 – 28:

> The present invention has as its object the provision of a medical instrument having a valve body having hollow rod-like members including hollow cylindrical

> members and/or solid columnar members of widely varied outer diameters inserted therethrough and held therein in a liquid-tight state, capable of **immediately** forming a proper closed state when the rod-like member or members are withdrawn, and having a simple construction.

Emphasis added. Clearly, modifying the valve member to include a solid-cross section would render the device of Matsumoto et al. unsatisfactory for its intended purpose.

In response to Applicants' previous arguments, the Examiner asserts in the Advisory Action:

> Py teaches the "hole", or slit (294), formed along the path of the piercing member (Fig 13b) will close upon itself due to the resiliency of the seal material (Py col 10, ll 26-33), which is analogous to Matsumoto's invention wherein the resiliency of the seal material causes the pre-formed slits to close and maintain a liquid-tight state (Matsumoto col 13, ll 45-51). Py further teaches although a liquid-tight seal may be formed by the resiliency of the seal material, vapors, gases, and/or liquid may be allowed to pass through the slit over time. Thus, it is advantageous to heat the seal to form a solid cross-section (Py col 10, ll 33-39). Therefore, by modifying Matsumoto in view of Py, a liquid-tight seal is still maintained upon immediate withdrawal of medical device inserted through the seal due to the resiliency of the seal material, and the combination additionally has the advantage of preventing vapors, gases, and/or liquid passing through the seal over time due to the solid cross-section formed in the seal.

The Examiner appears to acknowledge that Py discloses vapors, gases, and/or liquid may be allowed to pass through the slit generated by the piercing member over time. Py appears to disclose the seal material may be further altered using heat to recreate a generally solid member. However, Py does not appear to teach or suggest a self-sealing, solid cross-section sealing member maintains a vacuum within the inflation lumen. Py appears to disclose the cap may be sufficiently resilient to temporarily close itself, but Py does not appear to teach or suggest a vacuum is maintained with a self-sealing seal. Further, neither Matsumoto et al. nor Picha et al. appear to teach or suggest a seal that is self-sealing and has a solid cross-section such that the seal maintains a vacuum within the inflation lumen as currently claimed.

Independent claim 35, as amended, recites in part, "an inner surface of the lumen includes a chemical coating capable of binding air." None of Matsumoto et al., Picha et al., or Py, taken alone or in combination, appear to teach or suggest such a catheter including such a coating. As discussed above, Matsumoto et al. appear to disclose a medical device including a valve body. The valve body appears to be configured to allow an additional medical device,

such as a rod-like member, to pass through the valve body into the medical device. The valve body appears to include two slits crossing perpendicular to each other. When the additional medical device is not inserted into the medical device, the slits appear to maintain a substantially fluid tight seal. However, Matsumoto et al. do not appear to teach or suggest the medical device includes a chemical coating capable of binding air. Neither Picha et al. nor Py appear to teach that which Matsumoto et al. lack.

Therefore, for at least these reasons, none of Matsumoto et al., Picha et al., or Py, taken alone or in combination, appear to teach or suggest the device as claimed. As such, the teachings of Matsumoto et al., Picha et al. and Py are not sufficient to render claims 22 or 35 *prima facie* obvious. For at least these reasons, claims 22 and 35 are believed to be patentable over Matsumoto et al. and Picha et al. and withdrawal of the rejection is respectfully requested. For similar reasons and others, claims 24-28 and 30 which depend from claim 22 and include additional distinguishing features, are believed to be patentable over Matsumoto et al., Picha et al., and Py.

Conclusion

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Yiqun Wang et al.

By their Attorney,

Date: 11/17/2010

J. Scot Wickhem, Reg. No. 41,376
SEAGER, TUFTE & WICKHEM, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349